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PCT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P51330	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/09278	International filing date (day/month/year) 26 March 2003 (26.03.2003)	Priority date (day/month/year) 27 March 2002 (27.03.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): C07C 205/00, 229/00, 69/76, 51/23, 213/00, 43/00; C09B 11/02 and US Cl.: 560/20, 37, 42, 61; 562/418, 433, 442, 451; 564/315, 316, 317; 568/583, 584, 585		
Applicant SMITH KLINE BEECHAM CORPORATION		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 4 sheets, including this cover sheet.
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of — sheets.

- This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 25 September 2003 (25.09.2003)	Date of completion of this report 13 November 2003 (13.11.2003)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer <i>Valerie Bell-Harris</i> Taylor V. On Telephone No. 703-308-1235

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.

PCT/US03/09278

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed.

☒ the description:

pages 1-81 as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

☒ the claims:

pages 82-97, as originally filed

pages NONE, as amended (together with any statement) under Article 19

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

☐ the drawings:

pages NONE, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

☐ the sequence listing part of the description:

pages NONE, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/09278

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 5-18,23,28-38 and 46-58

because:

- ☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require international preliminary examination (*specify*):

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 5-18,23,28-38 and 46-58 are so unclear that no meaningful opinion could be formed (*specify*):

Claims 5-18, 23, 28-38, and 46-58 are improper multiple dependent claims under the PCT rule 6.4 (a).

- ☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.
☐ no international search report has been established for said claims Nos. _____

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/092

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims <u>1-4, 19-22, 24-27, 39-45</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>1-4, 19-22, 24-27, and 39-45</u>	YES
	Claims <u>NONE</u>	NO
Industrial Applicability (IA)	Claims <u>1-4, 19-22, 24-27, and 39-45</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-4, 19-22, 24-27, 39-45 meet the criteria set out in PCT Article 33(2)-(3), because the prior art Hoechst Aktiengesellschaft (GB 1538775) does not teach or fairly suggest the claimed compounds and the method of treating an LXR mediated disease by using the claimed compounds.

NEW CITATIONS

Sheet No

Box No. VIII(ii) DECLARATION: ENTITLEMENT TO APPLY FOR AND BE GRANTED A PATENT
The declaration must conform to the standardized wording provided for in Section 212; see Notes to Boxes Nos. VIII, VIII(1) to (v) (in general and the specific Notes to Box No. VIII(ii)). If this Box is not used, this sheet should not be included in the request.

Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent (Rules 4.17(ii) and 51bis.1(a)(ii)), in a case where the declaration under Rule 4.17(iv) is not appropriate:

SMITHKLINE BEECHAM CORPORATION is entitled to apply for and be granted a patent by virtue of the following:

an assignment from

Thompson, Scott K., 709 Swedeland Road, King of Prussia, Pennsylvania 19406, United States of America, dated May 28, 2003;

Kallander, Lara S., 709 Swedeland Road, King of Prussia, Pennsylvania 19406, United States of America, dated May 28, 2003;

Ma, Chun, 1150 River Road, Apartment 3G, Edgewater, New Jersey 07020, dated April 12, 2003;

Marino, Joseph P., 709 Swedeland Road, King of Prussia, Pennsylvania 19406, United States of America, dated May 28, 2003;

Lee, Dennis A., 709 Swedeland Road, King of Prussia, Pennsylvania 19406, United States of America dated May 30, 2003

This declaration is made for the purposes of all designations.

☐ This declaration is continued on the following sheet, "Continuation of Box No. VIII(ii)".

Form PCT/RO/101 (declaration sheet (ii)) (March 2001; reprint January 2003)

See Notes to the request form

Sheet No

Box No. VIII(iv) DECLARATION: INVENTORSHIP (only for the purposes of the designation of the United States of America). The declaration must conform to the following standardized wording provided for in Section 214; see Notes to Boxes Nos. VIII, VIII(1) to (v) (in general) and the specific Notes to Box No. VIII (iv). If this Box is not used, this sheet should not be included in the request.

**Declaration of Inventorship (Rules 4.17(iv) and 51bis.1(a)(iv))
for the purposes of the designation of the United States of America:**

I hereby declare that I believe I am the original, first and sole (if only one inventor is listed below) or joint (if more than one inventor is listed below) inventor of the subject matter which is claimed and for which a patent is sought.

This declaration is directed to the international application of which it forms a part (if filing declaration with application).

This application is directed to international application No. PCT/ (if furnishing declaration pursuant to Rule 26ter).

I hereby declare that my residence, mailing address, and citizenship are as stated next to my name.

I hereby state that I have reviewed and understand the contents of the above-identified international application, including the claims of said application. I have identified in the request of said application, in compliance with PCT Rule 4.10, any claim to foreign priority, and I have identified below, under the heading "Prior Application," by application number, country or Member of the World Trade Organization, day, month and year of filing, any application for a patent or inventor's certificate filed in a country other than the United States of America, including any PCT international application designating at least one country other than the United States of America, having a filing date before that of the application on which foreign priority is claimed.

Prior Applications: (prior to priority).....

I hereby acknowledge the duty to disclose information that is known by me to be material to patentability as defined by 37 C.F.R. §1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the PCT international filing date of the continuation-in-part.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name: **Scott K. Thompson**

Residence: **709 Swedeland Road, King of Prussia, PA 19406**
(city and either US state, if applicable, or country)

Mailing Address: **GlaxoSmithKline, Corporate Intellectual Property - UW2220, P.O. Box 1539**
King of Prussia, Pennsylvania 19406-0939

Citizenship: **United States of America**

Inventor's Signature: *Scott K. Thompson*
(if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent.)

Date: 4-11-03
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

☒ This declaration is continued on the following sheet, "Continuation of Box No. VIII(iv)".

Form PCT/RO/101 (declaration sheet (iv)) (March 2001; reprint January 2003)

See Notes to the request form

Sheet No.

Continuation of Box No. VIII(i) to (v) Declaration

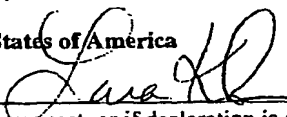
If the space is insufficient in any of Boxes Nos. VIII(i) to (v) to furnish all the information, including in the case where more than two inventors are to be named in Box No. VIII (iv), in such case, write "Continuation of Box No. VIII" (indicate the item number of the Box) and furnish the information in the same manner as required for the purposes of the Box in which the space was insufficient. If additional space is needed in respect of two or more declarations, a separate continuation box must be used for each such declaration. If this Box is not used, this sheet should not be included in the request.

Name: **Lara S. Kallander**

Residence: **709 Swedeland Road, King of Prussia, PA 19406**
(city and either US state, if applicable, or country)

Mailing Address: **GlaxoSmithKline, Corporate Intellectual Property - UW2220, P.O. Box 1539**
King of Prussia, Pennsylvania 19406-0939

Citizenship: **United States of America**

Inventor's Signature: 
(if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent.)


Date: 4/11/03
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

Name: **Chun Ma**

Residence: **1105 River Road, Apt. 3G, Edgewater, NJ 07020**
(city and either US state, if applicable, or country)

Mailing Address: **GlaxoSmithKline, Corporate Intellectual Property - UW2220, P.O. Box 1539**
King of Prussia, Pennsylvania 19406-0939

Citizenship: **China**

Inventor's Signature: 
(if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent.)

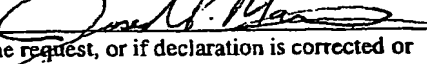
Date: 03-20-2003
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

Name: **Joseph P. Marino**

Residence: **709 Swedeland Road, King of Prussia, PA 19406**
(city and either US state, if applicable, or country)

Mailing Address: **GlaxoSmithKline, Corporate Intellectual Property - UW2220, P.O. Box 1539**
King of Prussia, Pennsylvania 19406-0939

Citizenship: **United States of America**

Inventor's Signature: 
(if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent.)

Date: 4-11-03
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

Sheet No

Continuation of Box No. VIII(i) to (v) Declaration

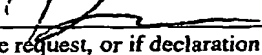
If the space is insufficient in any of Boxes Nos. VIII(i) to (v) to furnish all the informatino, including in the case where more than two inventors are to be named in Box No. VIII (iv), in such case, write "Continuation of Box No. VIII " (indicate the item number of the Box) and furnish the information in the same manner as required for the purposes of the Box in which the space was insufficient. If additional space is needed in respect of two or more declarations, a separate continuation box must be used for each such declaration. If this Box is not used, this sheet should not be included in the request.

Name: Dennis Lee

Residence: 709 Swedeland Road, King of Prussia, Pennsylvania 19406

Mailing Address: GlaxoSmithKline, Corporate Intellectual Property - UW2220, P.O. Box 1539
King of Prussia, Pennsylvania 19406-0939

Citizenship: United States

Inventor's Signature: 
(if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent.)Date: 5-30-03
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

Name:

Residence:
(city and either US state, if applicable, or country)Mailing Address: GlaxoSmithKline, Corporate Intellectual Property - UW2220, P.O. Box 1539
King of Prussia, Pennsylvania 19406-0939

Citizenship:

Inventor's Signature: _____
(if not contained in the request, or if declaration is corrected or added under Rule 26ter after the filing of the international application. The signature must be that of the inventor, not that of the agent.)Date: _____
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26ter after the filing of the international application)

10/508893

Rec'd PCT/PTO 22 SEP 2004

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/09278

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : C07C 205/00, 229/00, 69/76, 51/23, 213/00, 43/00; C09B 11/02
 US CL : 560/20, 37, 42, 61; 562/418, 433, 442, 451; 564/315, 316, 317; 568/583, 584, 585

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 560/20, 37, 42, 61; 562/418, 433, 442, 451; 564/315, 316, 317; 568/583, 584, 585

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
 STN-structural search has been done.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 1,538,775 (HOECHST AKTIENGESELLSCHAFT) 24 January 1979.	1-57

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

14 June 2003 (14.06.2003)

Date of mailing of the international search report

14 AUG 2003

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, Virginia 22313-1450

Facsimile No. (703)305-3230

Authorized officer

Taylor V. Oh

Telephone No. 703-308-1235